Bylaws of the Indiana University Kokomo Institutional Review Board (IRB)

Article I. NAME

The name of the committee is the Indiana University Kokomo Institutional Review Board (hereafter referred to as "the Board" or "Board").

Article II. OBJECT

The Board is an official Institutional Review Board, established under the Indiana University Federal Wide Assurance (FWA) with the Department of Health and Human Services (DHHS) for the Protection of Human Subjects in Research. This FWA document is a formal agreement between the University and the Federal government that commits the University to comply with applicable regulations governing the conduct of research involving human subjects.

Authority

The object of the Board is to protect the rights of human research subjects by:

1. ensuring compliance with and fulfillment of regulations relating to the Board, which have been promulgated by the United States, the State of Indiana, Indiana University, and other appropriate authorities;
2. fulfilling the policies and procedures entitled "Research Protocol Review: Guidelines and Polices for Investigators;" and
3. Reviewing, revising, and accepting where appropriate the minutes of the Board and the Exempt/Expedited Subcommittee of the Board.

Article III. MEMBERSHIP

The Chancellor of Indiana University Kokomo or designee shall submit recommendations for members of the Board to the Vice President for Research and Information Technology for final approval. The membership of the Board shall consist of:

1. no fewer than six members;
2. faculty members with expertise in more than one field;
3. male and female representation;
4. an individual with primary concerns in non-scientific areas;
5. an individual not affiliated in any manner with the university; and
6. an individual representing the Office of Research and Sponsored Programs at Indiana University Kokomo.

To insure the professional diversity or continuity of functioning of the Committee, the authority designated above shall appoint alternates to serve in the place of absent members when necessary. Members may be reappointed for an unlimited number of terms.

Article IV. OFFICERS

The Chancellor of Indiana University Kokomo or his/her designee shall recommend a tenured member of the faculty as chairperson of the Board for a two-year term to the Vice President for Research and Information Technology for his/her written approval. The chairperson shall be a voting member of the Board. The chairperson shall appoint a faculty member of the Board as vice chairperson to function in his/her absence.

1. The Chancellor of Indiana University Kokomo or his/her designee shall recommend an administrative co-chairperson of the Board biannually with the written approval of the Vice President for Research and Information Technology. The administrative co-chairperson shall be a voting member of the Board.
2. The officers of the Board may be reappointed for an unlimited number of years.
3. The Chancellor of Indiana University Kokomo or his/her designee as appropriate may appoint ex-officio members of the Board with the written approval of the Vice President for Research and Information Technology.

Article V. MEETINGS

1. The Board shall ordinarily meet once a month. The Chair shall determine the time, date, and place of the meetings or the Chair's designee and each member shall be notified in writing of the meeting schedule. If there is no business on the agenda five days prior to a scheduled meeting, the Chair or the Chair's designee may cancel the meeting and will notify members in writing.
2. The Chair may call a meeting at other than the scheduled monthly interval.
3. A simple majority of the membership of the Board shall constitute a quorum, which shall include at least one member whose primary concerns are in nonscientific areas. Determination of a quorum shall be subject to the following exceptions:

- a number of members and alternates equal to a majority of the members shall constitute a quorum;
- ex-officio members of the Board shall not be counted toward the establishment of a quorum.
- The quorum must be maintained during the meeting in order to conduct business. If a member or members leave the meeting and the quorum is disrupted, the meeting may not continue until such members return. If such members leave the meeting permanently and the quorum is disrupted, the meeting must adjourn. The meeting minutes shall reflect these occurrences.
- When a board member exits the room during deliberation of a proposal because of a conflict of interest, that member shall temporarily not be counted in the number necessary to reach a quorum.

Article VI. DECISIONS OF THE BOARD

1. Decisions by the Board shall be by majority vote of members and alternates in attendance at the meeting. A member or alternate having conflicting interest in a matter before the Board shall not vote on that matter. When a member or alternate is barred from voting because of a conflicting interest, said member or alternate shall not be counted in determining the number of votes needed for a majority, notwithstanding that the presence of said member or alternate has been counted to determine a quorum. Such member shall be absent from the room during the deliberation and vote.
2. Ex officio members and consultants shall not have voting rights on the Board.
3. Voting shall proceed openly, after an opportunity for full discussion and debate has been afforded.
4. Business may not be conducted by electronic mail or telephone poll. A member may participate in a face to face meeting by speaker phone or through videoconferencing media, since these mechanisms provide full real-time consideration of proposals. The minutes shall reflect this occurrence.

Article VII. SUBCOMMITTEES

1. The Chair may, from time to time, appoint subcommittees or ask members to execute various duties related to the objectives and policies of the Board, including, but not limited to:
    - assisting the Chair in preparation of the agenda for regular meetings of the Board;
    - performing periodic ongoing review of investigations previously reviewed by the Board or any of its subcommittees, including review of terminated investigations;
    - reviewing research proposals to determine whether such proposals may obtain expedited review by a subcommittee;
    - performing expedited review of research proposals;
    - assisting the Chair in reviewing modifications of previously approved research projects to determine whether such modifications warrant reconsideration of a project by the Board or a subcommittee;
    - reviewing reports of adverse and/or unexpected developments in previously approved research projects to determine whether such developments warrant reconsideration of a project by the Board or a subcommittee;
    - performing emergency review of research proposals when, in the opinion of the Chair, the employment of any other approval procedure may, because of the time required, seriously impair the mission of the University or the medical or other interests of any subject or potential subject of research; and
    - granting final approval to research proposals upon a determination that conditions required for approval by the Board or a subcommittee has been met.
2. Subcommittees shall be composed only of Board members or alternates and requested consultants.
3. Subcommittees may be comprised of any number of Board members or alternates, including the Chair, except as provided in Section D of this article.

4. A subcommittee appointed pursuant to Section A7 (emergency review) of this article shall have at least five members.
5. Subcommittees shall report any action taken to the next regular meeting of the full Board.

Article VIII. ACTION ON RESEARCH PROPOSALS

A simple majority vote shall be used to determine actions on proposals.

Exempt Studies: The faculty chairperson of the Board or a designee will review research proposals that are submitted as exempt.

1. The Chair or designee will determine whether a proposal meets the criteria for an exempted study. If it does not, the proposal must be re-submitted in the correct format for the appropriate level of review.
2. Determinations regarding exempted study proposal status shall be communicated in writing to the principal investigator.
3. Exempted studies do not require Board approval.
4. Determinations regarding exempted study proposals shall be communicated to the Board at its next regularly scheduled meeting.
5. Records of every exempted study proposal shall be maintained in the Office of Research and Sponsored Programs at Indiana University Kokomo.

Expedited Studies: The Board may delegate review of proposals submitted as expedited to a subcommittee.

1. The subcommittee will determine whether a proposal meets the criteria for an expedited review. Proposals requiring a full review must be re-submitted to the Board in the correct format.
2. The subcommittee may approve, grant provisional approval, or table an expedited proposal.
3. Findings of the subcommittee shall be communicated to the principal investigator in writing, and a written record maintained in the Office of Research and Sponsored Programs at Indiana University Kokomo.
4. When communicating findings to the principal investigator, items to be addressed shall be enumerated clearly.
5. Tabled expedited proposals must be re-submitted to and received by the subcommittee.
6. When provisional approval has been granted, the subcommittee may require re-submission to the subcommittee or to the Board chair for final approval upon showing that the conditions for approval have been met.

Full Review Studies: The Board shall review all proposals meeting the criteria for Full Review.

The Board may approve, grant provisional approval, table, or disapprove a proposal.

1. Findings of the Board shall be communicated to the principal investigator in writing and a written record maintained in the Office of Research and Sponsored Programs at Indiana University Kokomo.
2. When communicating findings to the principal investigator, items to be addressed shall be enumerated clearly.
3. Tabled proposals require re-submission and review by the Board.
4. When provisional approval has been granted, the Board may delegate the review of the amended material to a subcommittee or to the Board chair for final approval upon determination that the conditions for approval have been met.

Other Action on Research Proposals

1. The Board or subcommittee shall review research proposals submitted to it and shall periodically conduct ongoing review of approved research projects. If a study is inadvertently terminated, it may be reactivated within 60 days without submitting it to the Board as a new study.
2. Consideration will be given during the approval process by the Board to determine the review frequency for the study.
3. The Board may, upon the request of an investigator or on its own initiative, reconsider any proposal and reverse its own determination or that of a subcommittee; however, proposals that are tabled or denied approval by the Board cannot be resubmitted in any form for approval by a subcommittee in an attempt to bypass the Board.
4. The Board may appoint a subcommittee to review amendments to and continuing reviews of projects approved by the Board. Such delegated review shall be deemed to be the review of the Board upon report to and approval by the Board.

Article IX. PARTICIPATION OF NON-MEMBERS

1. The meetings of the Board may be attended by persons who are not members with the consent of the Chair. A person who is not a member of the Board shall, with the consent of the Chair, be permitted to express views or opinions and offer comments, explanatory or otherwise, to the Board.
2. Consultants with competence in special areas may be invited to assist in the reviews and research issues which require expertise different from that available on the Board.
3. When research investigators are present during deliberation of their proposals, the investigators shall be asked to leave the room during a vote.

Article X. PROCEDURE FOR BOARD MEETINGS

1. The Board may delegate authority to the Office of Research and Sponsored Programs at Indiana University Kokomo to initially review and process all research-related documentation to assure completeness for submission to the Board or subcommittees.

2. The members of the Board shall be furnished with advance copies of the agenda for its regular meetings.
3. The Chair or the Chair's designee appointed for that purpose should prepare the agenda.
4. Except as provided in Section G of this Article, no decision shall be taken on a research proposal unless it is included in the agenda.
5. A research proposal, unless suitable for delegated expedited review, shall be placed on the agenda for the next scheduled meeting if such proposal has been received at least two weeks in advance of the meeting, or, if the research proposal has been received less than two weeks in advance of the meeting, at the discretion of the Chair.
6. In addition to review of research proposals not delegated to a subcommittee for expedited review, the agenda shall include the following:

    - review of minutes of the previous Board meeting;
    - review of minutes from the Board mentioned in Section B of Article II, if available;
    - review of previously approved research projects that have been modified or of the report of the subcommittee appointed to review such modifications;
    - review of previously approved research projects in which unanticipated difficulties have occurred or of the report of a subcommittee appointed to review such projects and difficulties;
    - ongoing review of previously approved projects or of the report of a subcommittee appointed to review such matters;
    - review of the report of any subcommittee appointed to perform expedited review;
    - review of the report of any subcommittee appointed to perform emergency review;
    - review of terminated projects or of the report of a subcommittee appointed to review such projects; and
    - such other matters the Chair or any member shall consider appropriate.

7. Whenever, in the opinion of the Chair or Vice Chair and a majority of the members and alternates constituting the quorum of a meeting, delay in making a decision on a research proposal will seriously impair the mission of the University or the medical or other interests of a subject or potential subject of research, a decision may be reached on the proposal notwithstanding that the proposal has not been placed on the agenda.

Article XI. MINUTES

1. The Chair shall prepare, or cause to be prepared, minutes of each meeting that shall be furnished to each member of the Board.
2. The Chair shall preserve, or cause to be preserved, an archive of the minutes of meetings.

Article XII. AMENDMENTS

A member of the Board may propose amendments to these Bylaws. The amendment may be adopted by majority vote.

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